March 3, 2004

Via fax and UPS

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2003D-0386
Draft Guidance for Industry on Formal Dispute Resolutions: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice [Federal Register Volume 68, No. 172, page 52777, September 5, 2003]

Dear Sir/Madam:

Aventis Pharmaceuticals Inc. appreciates the opportunity to comment on the above-referenced draft guidance entitled "Formal Dispute Resolutions: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice".

In the draft guidance, the Agency describes a formal, two-tiered dispute resolution process intended to resolve disputes of scientific and technical issues relating to current good manufacturing practice (CGMP) that arise during FDA inspections of pharmaceutical manufacturers.

We offer the following comments/clarification for your consideration.

Lines 71-85: *Section II. SCOPE OF THE GUIDANCE*
"The policies and procedures described in this guidance document cover all disputes on scientific or technical issues related to CGMP that arise as the result of CGMP and preapproval inspections (PAI) for manufacturers of veterinary and human drug products and CGMP inspections for human biological drug products. For disputes that arise during prelicense and preapproval inspections for human biological drug products or for application review issues that arise during PAI inspections for human or veterinary drug products, the existing CDER/CBER and CVM guidances listed in Section I of this document should continue to be used.

This guidance does not cover disputes over procedures or administrative matters that may arise during the inspection process. At any time, a manufacturer may formally raise a procedural or administrative matter with ORA or with the CDER, CBER or CVM

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Ombudsman. The procedures described in this guidance do not apply to such informal dispute resolution through the CDER, CBER, or CVM Ombudsman."

Recommendation: Our major concern is that the scope of the guidance is not clear. The scope of the guidance indicates that it covers disputes related to PAI inspections for human or veterinary products. The scope also indicates that it does not cover disputes over procedures or administrative matters during the inspection process. Does this mean that disputes that arise during inspections related to active pharmaceutical ingredients (API) are not covered under this guidance? Further, does this also mean that disputes that arise during inspections related to devices are not covered under this guidance? For clarity, we suggest adding text to indicate the full scope of this guidance.

On behalf of Aventis, we appreciate the opportunity to comment on the *Draft Guidance for Industry on Formal Dispute Resolutions: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice* and are much obliged for your consideration.

Sincerely,

Steve Caffé, M.D.
Vice President, Head US Regulatory Affairs